The Regulation for Medical Device Classification

Article1 This regulation is stipulated in accordance with the *Directive to Medical Device Administration* to standardize the classification of medical devices.

Article2 "Medical devices" refer to those instruments, equipment, tools, materials and other objects, including the software attached to them, that are designed to be used either independently or in combination on human body. These devices are used for:

1. Prevention, diagnosis, treatment, monitoring or remission of diseases;
2. Diagnosis, treatment, monitoring, remission or compensation of injury or physical disability;
3. Research, replacement or adjustment of anatomical or physiological process;
4. Control of pregnancy.

Basically, the effect of these devices on human body is not achieved through means of pharmacology, immunology or metabolism; though they might be resorted to in order to bring about certain supplementary effect.

Article3 This regulation is meant to direct the formulation of *The Category of Medical Device Classification* as well as to determine the classes of newly registered products.

Article 4 The classification of medical devices should take into account their respective structural characteristics, form of operation as well as conditions for use.

Specifically, their classification should follow *Criteria for Medical Device Classification* as shown in the appendix.

Article 5 Guidelines for Medical Device Classification

1. The structural characteristics of medical devices

According to their respective structural characteristics, medical devices are divided into active and passive devices.

2. The form of operation of medical devices

Medical devices are designated into different forms of operation in accordance with their intended purposes.

1) Passive devices in terms of their form of operation can be classified as device used for transportation and storage of pharmaceutical fluid, device for alteration of body fluid, device for medical adhesion, surgical device; reusable surgical device, disposable surgical device, implantable, device for sterilization and cleaning, patient care device, device for contraception and

birth control, in vitro diagnostic reagent, as well as other passive contacting device or passive supplementary device.

2) Active devices in terms of their form of operation can be classified as device for treatment through energy, diagnostic monitoring, body fluid transportation and ionized radiation, laboratory use and medical sterilization; as well as other active contacting device or active supplementary device.

1. The conditions for use of medical devices:

Medical devices may be divided into contacting and non-contacting devices based on their conditions for use, which include the possible injuries they might entail as well as their impact on the medical treatment.

1) Contacting or inserted devices

a. Term of use: temporary use, short – term use, long-term use;
b. Particular parts of the human body being contacted:
skin, cavity and tract; trauma or body tissue; blood circulation system or central nervous system;
c. The degree of injuries caused by malfunction of active devices:
minor injuries, injuries, material injuries.

2) Non-contacting Devices

The impact these devices have on human body ranges from: little or no impact, remote impact, material impact.

Article 6 Principles for Medical Device Classification

1. The classification of medical devices should be conducted in accordance with *The Criteria for Medical Device Classification*.

2. The criteria for medical device classification are based on the intended purpose and the form of operation of a medical device. Should the intended purpose of a product be different from its form of operation, its class shall be determined respectively.

3. For those medical devices to be used in combination with each other, the classification of each part should then be dealt with separately. Accessories to medical devices should be classified independently from the master device respecting their own conditions.

4. For those medical devices to be used on particular parts of the human body, the classification should be conducted on the basis of the risks involved in their intended purposes and form of operation.

5. Software that controls the functions of the medical device should be designated to the same class of its associated medical device.

6. Should one medical device pertain to two classes at the same time, the higher one is adopted.

7. Those products that are designed to monitor or affect the major functions of a medical device should be designated to the same class of the device being monitored or affected.

8. The State Pharmaceutical Administration shall readjust as it sees fit the classification of certain medical devices that call for special administration.

Article 7 The State Pharmaceutical Administration shall take charge of the classification of medical devices. In cases when a medical device fails to be designated according to *The Category of Medical Device Classification*, its classification then should be based on *The Regulation for Medical Device Classification* at the discretion of the provincial pharmaceutical administration, the result of which should be submitted to the State Pharmaceutical Administration for approval.

Article 8 Interpretation of Certain Terms Covered by This Regulation

1. *Intended purpose:* the desired effect of a medical device that is illustrated in its product specification, label or materials for publicity.

2. *Risk:* the possible injuries that may be caused by the medical device and the seriousness of the injury.

3. *Term of use:*

   a. Temporary Use: the intended term for consecutive use of the device is within 24 hours;
   b. Short-term Use: the intended term for consecutive use of the device ranges from 24 hours to 30 days;
   c. Long-term Use: the intended term for consecutive use of the device is above 30 days.
   d. Term for consecutive use: the actual number of non-stopping working hours of a device in accordance with its intended purpose.

4. Parts being operated upon and the device:

   a. Non-contacting devices: devices that do not directly contact the body of a patient;
   b. Surface contacting devices: including devices contacting the following parts of the human body:

      1) skin: devices that only contact the surface of the unwounded skin;

      2) mucous membrane: devices that contact the mucous membrane;

      3) surface of injuries: devices that contact the wounded area or the surface

of other injured areas.

e. Devices for surgical insertion: devices that are entirely or partly inserted into the body through the skin by surgery contacting the following parts of the human body:

1) blood vessel: inserted devices contacting a point on a blood vessel as a channel to the blood vessel system.

2) tissue/bone/dentinum: devices and materials that are inserted into the tissue, bones as well as endodontium/dentinum system.

3) blood circulation: devices that contact the blood circulation system.

5.*Implantables:* devices that are entirely or partly inserted into the cavity or tract of the human body through surgeries. These devices either remain in the body over a long period of time, or partly remain in the body for at least 30 days.

6. *Active device:* any medical device that operates on electric power or other forms of energy excluding those produced by human body or gravity.

7. *Reusable surgical device:* devices that are used to conduct such procedures during a surgery as excision, boring, sawing, clutching, scraping, clipping, drawing and clamping without having to resort to any active device and that can be reused after certain treatment.

8.*Central Circulation System:* referring to a number of vessels of the blood circulation system including pulmonary artery, aorta, coronary artery, carotid artery, cerebral artery, cardiac vena, upper cavity vena*, and lower cavity vena*.

5. *Central Nervous System*: referring to cerebrum, meninx and medulla spinalis,

Article 9 The power of interpretation of this regulation pertains to the State Pharmaceutical Administration.

Article 10 This regulation begins to take effect on 10th April, 2000.

Criteria for of Medical Devices Classification

		Contacting or Inserted Device A								
	Form of Operation	**Temporary use-1**			**Short-term use-2**			**Long-term use-3**		
		Skin/ Cavity and Tract	Trauma /Tissue	Blood Circulation/ Central Circulation	Skin/ Cavity and Tract	Trauma /Tissue	Blood Circulation/ Central Circulation	Skin/ Cavity and Tract	Trauma /Tissue	Blood Circulation/ Central Circulation
	1 Device for transportation and storage of pharmaceutical fluid	2	2	3	2	2	3	2	3	3
	2 Device for alteration of blood and body fluid			3			3			3
	3 Device for medical adhesion	1	2	2	1	2	2			
	4 Surgical device (inserted)	1	2	3	2	2	3	2	3	3
	5 Reusable surgical device	1	1	2						
Passive Device A	6 Disposable surgical Device	1	2	3	2	3	3	2	3	3
	7 Implantable							3	3	3
	8 Device for contraception and birth control	2	2	3	2	3	3	3	3	3
	9 Device for sterilization and cleaning	2	2	2	2	2	2	2	2	2
	10 Other contacting passive device	1	2	3	2	2	3	2	3	3
	Form of Operation	**Minor Injuries-1**			**Injuries-2**			**Material Injuries-3**		
Active Device B	1 Device for treatment through energy		2						3	
	2 Device for diagnostic monitoring		2			2			3	

	3 Device for body fluid transportation	2		3
	4 Device for ionized radiation	2	3	3
	5 Other general active device	2	2	
Passive Device A			**Non-contacting Device B**	
	Form of Operation	**Little or No Impact**	**Remote Impact**	**Material Remote Impact**
	1 Device for patient care	1	2	
	2 In vitro diagnostic reagent	1	2	3
	3 Other supplementary device	1	2	
Active Device B	**Form of Operation**	**Little or no impact**	**Remote impact**	**Material Remote Impact**
	1 Device for laboratory use	1	2	
	2 Device for sterilization	1	2	
	3 Other supplementary device	1	2	

Instructions for use:

1. This table is an appendix to *The Regulation for Medical Device Classification* and applies to the classification of specific products. The mark "-" indicates that there is no such classification yet.
2. The number or the mark in the header column signifies the code for this column, and therefore codes for different parts of human body in turn are shown as "1", "2", "3", etc. For example, the code for a passive inserted surgical device contacting the tissue for short-term use can be notified as AA4-22.

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